

<b>STUDY TITLE</b>	<b>MeRes-1 Extend “A Prospective, Multinational, Multicenter, Single arm, Open label, Pilot Clinical Study of MeRes100 Sirolimus eluting Bioresorbable Vascular Scaffold System in the Treatment of <i>de-novo</i> Native Coronary Artery Lesions</b>
<b>STUDY POPULATION</b>	<b>Subject with Coronary Artery Disease and underwent PCI</b>
<b>PRINCIPAL INVESTIGATOR</b>	Datuk Dr. Rosli Mohd Ali
<b>STUDY COORDINATOR</b>	Renobastian Nur Syamsi Contact number 03 – 2617 8200 ext 8451
<b>START DATE</b>	5 May 2016
<b>END DATE</b>	TBA
<b>INCLUSION</b>	<p>General inclusion :-</p> <ul style="list-style-type: none"> <li>• Male or female subjects age 18 years or more</li> <li>• Subjects is able to sign written informed consent form</li> <li>• Subjects with symptomatic myocardial ischemia, chronic stable angina</li> <li>• The patient has planned intervention of a single de novo lesion in native epicardial vessel</li> <li>• Subject who is an acceptable candidate for Coronary Artery bypass Grafting (CABG)</li> <li>• Subject is not participating in any other clinical investigation/study and agrees not to participate in any other clinical investigation/study for a period 3 years following the index procedure</li> <li>• Subject must agree to undergo all clinical investigation plan-required follow-up visits, angiograms and OCT as per protocol</li> </ul> <p>Angiographic Inclusion :-</p> <ul style="list-style-type: none"> <li>• Subject with maximum two treatable de novo lesions located maximum one per native epicardial vessel located in major artery or branch, with reference vessel diameter between 2.75, 3.00 and 3.5 mm by on line QCA</li> <li>• Target lesion length 20 mm or less</li> <li>• Subjects with Lesion(s), with a visually estimated stenosis of 50% or more and less than 100% with a TIMI flow of 1 or more</li> </ul>

## EXCLUSION

### General Exclusion :-

- Subjects unable to provide written informed consent
- Pregnant or nursing mother and those who plan pregnancy during the clinical investigation (female patients must have a negative pregnancy test done within 7 days prior to the index procedure and effective contraceptive must be used during participation in this clinical investigation)
- Subject with known allergy to Poly-L-Lactide (PLLA), Poly-D,L-Lactide (PDLLA), Sirolimus (Rapamycin) or its any analog or derivative, clopidrogel, ticlopidine, prasugrel, contrast media, platinum, ticagrelor, and any drug in dual antiplatelet therapy including aspirin, both heparin and bivalirudin
- Subject diagnosed with Acute MI (AMI) within 7 days preceding the index procedure, as indicated by elevated levels of cardiac enzymes and/or ST segment changes in (ECG)
- Subject with history of previous revascularization procedures including CABG and Coronary Intervention (PCI)
- Subject with vascular aneurysms, cardiac arrhythmias, congestive cardiac failure having LVEF less than 30%, cardiac tamponade
- Recipient of an organ in an organ transplant procedure or is on a waiting list for any organ transplant
- Subjects receiving immunosuppression therapy or having known immunosuppressive or autoimmune disease
- Subjects with history of stroke, Cerebro Vascular Accident (CVA) or Transient Ischemic neurological Attack (TIA). Patients with renal insufficiency where creatinine levels are more than 1.3 mg/dL, known aplastic anemia, chronic liver disease, platelet count less than 100,000 cells/mm<sup>3</sup>, a WBC of less than 3,000 cells/mm<sup>3</sup>
- Subjects planned for elective surgery within the first 12 months after the procedure that will require discontinuing dual antiplatelet therapy
- Subject has a history of bleeding diathesis or coagulatory disease, refuses blood transfusion, significant GI or urinary bleed within the past 12 months
- Subject having extensive peripheral vascular disease that precludes safe 6F sheath insertion
- Subject having a history of paradoxical exercise induced vasoconstriction that is consistent with myocardial bridging in the coronary anatomy
- Subjects participating in another clinical investigation
- Subjects with short life expectancy such as cancer, HIV/AIDS, or other co-morbid conditions that would limit compliance with the follow-up schedule of the study

### Angiographic Exclusion :-

- Subjects who are non-candidates for PCI

- Any of the lesions meets any of the following criteria :
  - Aorta-ostial location (within 3mm)
  - Lesion located in left main coronary artery
  - Lesion located within 2 mm of the LAD or LCx
  - Lesion that involves a bifurcation with a side branch 2 mm or more in diameter and ostial lesion more than 40% stenosed by visual estimation or side branch requiring intervention
  - Total occlusion (TIMI flow 0), prior to wire crossing
  - Extreme tortuosity proximal to or within the lesion
  - Lesions having heavy calcification
  - Extreme angulation (90% or more) proximal to or within the lesion
- Evidence of previous revascularization :
  - Previous PCI with or without restenosis from previous intervention
  - Arterial or venous graft with or without lesion located within the graft or distal to a diseased arterial or saphenous vein graft
- The target vessel contains visible thrombus
- Another (clinically significant or potentially significant) lesion left untreated within target vessels (including side branch) or another significant vessel
- Subject requiring or potentially requiring interventional procedures other than pre-dilatation and study device implantation and post dilatation